Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification No. 18293: 1,3-Dioxolane-4-methanol, 2-methyl-2-(2-methylpropyl)

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of that Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance Identity

1,3-Dioxolane-4-methanol, 2-methyl-2-(2-methylpropyl) (Chemical Abstracts Service Registry No. 5660-53-7) is a chemical that can be classified as an organic alkyl dioxolane.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as a component of cleaning fluid in oil field drilling operations. Potential uses may include consumer cleaning and degreasing products.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is expected to be persistent in water based on hydrolysis data indicating that the substance is stable under environmental conditions. The substance is not expected to bioaccumulate based on its low predicted bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information, the substance has low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration >100 mg/L). Calculation of the predicted no-effect concentration was not considered necessary given the low ecotoxicity.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is

not expected because no significant releases are anticipated. Therefore, a predicted environmental concentration for notified activities was not calculated.
Based on the predicted low toxicity to aquatic organisms and low potential for environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information and surrogate data on structurally related chemicals, the substance is expected to have a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg-bw) and a low potential for subchronic and reproductive toxicity following repeat oral doses in mammalian test animals (no-observed-adverse-effect level >1000 mg/kg-bw/d). It is not a sensitizer. It is not mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a component of cleaning fluid in oil field drilling operations, direct exposure of the general population is not expected. When used for other potential uses such as consumer cleaning and degreasing products, direct exposure of the general population is expected to be mainly by dermal contact and inhalation at moderate to high levels. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Based on the low overall human health hazard, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

Assessment Conclusion

When used as notified or for other identified potential uses, the substance is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

A conclusion under CEPA, on this substance, is not relevant to nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for workplace use.